

MTF Formulary Management for GABA Analogs

Department of Defense Pharmacoeconomic Center

Uniform Formulary Decision: The Director of TMA has approved the recommendations from the 14 February 2006 DoD P&T Committee meeting regarding formulary status of GABA Analogs used in Neuropathic Pain on the Uniform Formulary (UF) and Basic Core Formulary (BCF). Conversion from non-formulary agents to a BCF or UF drug or establishment of medical necessity may commence 26 April 2006 and must be completed by 28 Jun 2006.

Uniform Formulary (UF) Agents		Non-Formulary Agents (NF)
GABA drugs on BCF MTFs <u>must</u> have on formulary	GABA drugs not on BCF MTFs <u>may</u> have on formulary	GABA drugs MTFs <u>must</u> <u>not</u> have on formulary
Gabapentin (Neurontin and generic)	Tiagabine (Gabitril)	Pregabalin (Lyrica)

- The most cost effective GABA analog is gabapentin. The differences in clinical characteristics between Lyrica and gabapentin, including linear kinetics, titration schedule, and BID dosing in post herpetic neuralgia (PHN), did not provide sufficient clinical advantage for Lyrica outweigh its higher cost.
- The efficacy of gabapentin and Lyrica for treating pain associated with either diabetic peripheral neuropathy (DPN) or PHN appears similar. Like gabapentin, Lyrica is dosed TID for DPN; however, Lyrica may be dosed BID in PHN. The safety and tolerability profiles of gabapentin and Lyrica are similar.
- Patients may be titrated to an effective dose more rapidly with Lyrica vs. gabapentin, but onset of efficacy for DPN and PHN is similar, approximately 1-2 weeks.
- At higher doses gabapentin exhibits decreased bioavailability, in contrast to Lyrica's bioavailability (> 90% at all doses). However, Lyrica's bioavailability has not been shown to improve pain relief at higher doses. In fact, the manufacturer of Lyrica does not recommend dosages greater than 300 mg/d for DPN because 600 mg/d has not been shown to significantly improve pain scores and has been associated with a greater incidence of adverse effects.
- Gabapentin is the only GABA analog that has shown modest efficacy in treating other types of neuropathic pain (e.g., phantom limb pain). There is anecdotal reports within the MHS demonstrating efficacy as adjunctive therapy for phantom limb pain; however there is no published data.
- Lyrica is the only drug in this class that is a controlled substance, schedule V.
- Gabapentin, Lyrica, or Gabitril appear to be similarly effective for adjunctive treatment of partial seizures.
- Effective dosing range for gabapentin for neuropathic pain relief appears to be 1800 mg to 2400 mg per day.
- Lyrica is the least cost-effective agent at the MTF. MTFs should only dispense NF drugs for patients who cannot be treated with gabapentin for neuropathic pain and partial seizures or Gabitril for partial seizures. MTFs must use the medical necessity criteria established by the DoD P&T Committee. The criteria are available on the TRICARE Pharmacy website: <http://www.tricare.osd.mil/pharmacy/medical-nonformulary.cfm>. A Microsoft Word version of the TMOP/TRRx Medical Necessity form adaptable for MTF use is available on RxNET.

GABA Analogs Average Daily Drug Cost in MHS		
Drug	Weighted Average Daily Cost per Day of Treatment (January 2006) ^{ab}	
Basic Core Formulary GABA Analog	MTF Costs	System Cost ^c
Gabapentin	\$0.60	\$2.22
Other Uniform Formulary GABA Analog available for inclusion on MTF formularies		
Tiagabine (Gabitril)	\$1.99	\$5.06
Non-formulary GABA Analog		
Pregabalin (Lyrica)	\$2.99	\$4.46

^a Post-decision prices; actual price may vary slightly due to MTF-specific Prime Vendor discounts and/or fees

^b MTFs are prohibited from entering into any incentive pricing agreements in any form with GABA drug pharmaceutical manufacturers to receive additional discounts.

^c System costs are the average weighted daily cost across all 3 points of service.

References

- For the full clinical review of the GABA Analogs and for discussion about UF decisions, log onto RxNET (the PEC's webforum) www.dodrxnet.org (under "File Library" forum, "DoD P&T Library" folder).
- Current/future drug classes under review by the DoD P&T Committee: www.pec.ha.osd.mil/PT_Committee.htm
- TRICARE website for information on the Uniform Formulary: www.tricare.osd.mil/pharmacy
- TRICARE Formulary Search Tool: www.tricareformularysearch.org

POC: For more information email: PECUF@amedd.army.mil.